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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,961	06/04/2001	Puranam U. Sarma	2761-0147P	5257

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EXAMINER
CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	10

DATE MAILED: 03/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/871,961	SARMA ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 8/28/01 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/189,938 .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant is advised that the date of the signature for inventor Katti has not been provided on the original oath/declaration.

Claims Rejections-35 USC 112

Claims 1-17 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement of claims 7 and 24 requires the availability of ATCC AF-102, ATCC-42202. The biological materials claimed have not been fully disclosed or the materials required to construct the claimed biological material have not been shown to be publicly known and freely available. The deposit should have been made in accordance with MPEP 2402. In order to certify that the deposit meets the criteria set forth in MPEP 2402, applicants may provide assurance of compliance by an affidavit or declaration, or by an attorney of record over his or her signature and registration number. Applicant is advised that the Patent and Trademark Office accepts Budapest approved deposits, as long as assurance is provided that the deposited materials will be irrevocably available with no restrictions upon issuance of a patent.

Claims 1-17 are directed to a method of diagnosis of apsergillosis comprising collecting body fluid, incubating with one or more peptides, and separating the unbound antibodies that should then be used in an ELISA detection assay. However, these steps are confusing in that it

would seem that the peptides would form a complex with the antibodies in the fluid and that if this complex is removed, the necessary complex used in the ELISA assay would be missing. Therefore, how can the remaining steps be diagnostic? The specification indicates that the peptides referred to in step (b) are diagnostic because they bind antibodies in the sera of patients (see for example page 5), yet these complexes do not appear to be present in the diagnostic steps of the method as written. Perhaps applicant intended that the antibodies referred to in step (d) are not the unbound antibodies of step (c). However, if the sera antibodies bound to the peptide(s) in step (b) were intended by the recitation of "antibodies obtained" the claims are unclear and furthermore it would appear that these antibodies would remain complexed to the indicated peptides and not bind to the allergens/antigens coated on the ELISA plate. Please clarify.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it is unclear whether the method is intended to use combinations of peptides. Step (c) concerns residual unbound antibodies but step (b) does not require any antibodies.

Claim 18, step (b) refers to "peptides" where as the preamble refers to a single peptide.

Claim 7 and 24 are confusing in reciting "have some characteristics ATCC strain AF-102; ATCC-42202." This phrase is not grammatically correct and does not define the characteristics that are intended to be encompassed. The claims are further confusing in that the

base claims upon which they depend do not require *Aspergillus fumigatus* strains for peptide synthesis.

Claims 8 and 25 are confusing in that there is neither antecedent basis nor requirement for epitope identification in claims 1 and 18.

Claims 10-12 and 27-29 do not further limit the method as they address properties of the peptides and the limitations do not clearly limit the peptides encompassed. These functional limitations do not provide any structural changes to the peptides and the specification appears to indicate that each of SEQ ID Nos. 1-6 would have these properties.

Claims 13-17 and 30-34 are confusing for the following reasons: Claims 13 and 30 recite DNA sequences encoding peptides being defined as in claim 1, yet claim 1 does not require any DNA sequences. Claims 14 and 15 refer to nucleic acid probes and claim 34 refers to nucleic acid sequences which are not required by claim 18. Claims 16-17 and 33 are confusing in that they depend upon method claims but appear to be directed to products.

Claim 32 does not appear to be properly dependent as it refers to multiple peptides that are not required by claim 18. Claim 18 appears to be directed to use of SEQ ID No. 2.

No Claim is Allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10 A.M. to 6 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
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AU1631

March 15, 2002

Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow